UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,904	09/30/2003	Cecil Kost	MMSI121562	8999

26389 7590 04/28/2011

CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC
1420 FIFTH AVENUE
SUITE 2800
SEATTLE, WA 98101-2347

EXAMINER
LASTRA, DANIEL

ART UNIT	PAPER NUMBER
3688	

NOTIFICATION DATE	DELIVERY MODE
04/28/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efiling@cojk.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CECIL KOST, TIMOTHY CHROBUCK, SCOTT M. KING, DAVID V. TOVREA, SUSAN T. BURROWS, STEVEN E. SINGER, and ZACHARY K. HECTOR

Appeal 2009-006398
Application 10/674,904
Technology Center 3600

Before MURRIEL E. CRAWFORD, ANTON W. FETTING, and BIBHU R. MOHANTY, *Administrative Patent Judges*.

MOHANTY, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

The Appellants seek our review under 35 U.S.C. § 134 (2002) of the final rejection of claims 1-2, 4-10, 16-25, 31, 33-45, and 51-55 which are all the claims pending in the application. We have jurisdiction under 35 U.S.C. § 6(b) (2002).

SUMMARY OF THE DECISION

We AFFIRM-IN-PART.

THE INVENTION

The Appellants' claimed invention is directed to a system and method for drug sample fulfillment distribution (Spec. 4:5-6). Claim 1, reproduced below with the numbering in brackets added, is representative of the subject matter of appeal.

> 1. A system for promoting pharmaceutical drugs, comprising:
>
> a computer-readable set of brand rules for guiding a distribution of drug samples of a drug to cause a [1] prescriber's drug sample availability and characteristics while a member of one brand Web site to be different from the same prescriber while a member of another brand Web site; [2] and
>
> a computer-implementable drug sample fulfillment platform that is Web-based for implementing the set of brand rules to allow a prescriber to obtain drug samples to dispense to a patient without the use of a sales representative, the computer-implementable drug sample fulfillment platform mating with either the brand Web site or the another brand Web site depending on an exchanged transaction that includes [3] a prescriber identifier and a partner identifier so as to open the computer-implementable drug sample fulfillment platform within the brand Web site or the another brand Web site, [4] the computer-implementable drug sample fulfillment platform electronically notifying the prescriber about the availability of drug

samples, the brand Web sites being neither a pharma Web site nor a Web site maintaining the computer-implementable drug sample fulfillment platform.

THE REJECTIONS

The Examiner relies upon the following as evidence in support of the rejections:

Feeney, Jr.	US 2002/0032582 A1	Mar. 14, 2002
Peyrelevade	US 2003/0120550 A1	Jun. 26, 2003

Medmanage (TM) Leads Shift in Drug Sampling Practices Online Vouchers, PR Newswire, Sep. 17, 2001 (Dialog file: 16:08993926).

Rx Centric and Medmanage Systems Partner to Expand Physician Use of Innovative Online Drug Sampling-Alliance Gives Pharmaceutical Companies Broader Physician Access to Drug Detailing and Sampling Programs, Business Wire, Mar. 20, 2001 (Dialog file: 610:00483951).

MedManage tracks troublesome pills samples, Carol Tice, Pudget Sound Business Journal, May 19, 2000 (Dialog file: 635:2075728).

For consumers free samples are a virtual reality: Pharmaceutical samples were once strictly passed from manufacturer to physician to patient, but online marketing tactics are rearranging that order, Med Ad News, January 2002 (Dialog file 9: 02648296).

Samples of the future (Estimated retail worth of drug samples dispensed in 2000 was $7.95 bill or some 50% of the promotional spending; new technology to improve monitoring), Med Ad News, July 2001, Dialog file 9:02536449).

iPhysicianNet and MedManage Systems Partner to Offer a New Electronic and Voucher Sampling Service to Thousand of U.S. Physicians, PR Newswire, April 24, 2001 (Dialog file: 20:16322132).

The following rejections are before us for review:

1. Claims 1, 6, 16, 21, 31 are rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description and reasonably conveying possession of the claimed invention.

2. Claims 1, 6, 16, 21, 31 are rejected under 35 U.S.C. § 112, second paragraph.

3. Claim 1 is rejected under 35 U.S.C. § 103(a) as unpatentable over MedManage and Peyrelevade[1].

4. Claims 2, 4-5, 16-20, and 51 are rejected under 35 U.S.C. § 103(a) as unpatentable over MedManage, RxCentric, Sample of the Future, and Peyrelevade.

5. Claims 6-10, 21-25, 31, 33-43, 45, and 53-55 are rejected under 35 U.S.C. § 103(a) as unpatentable over iPhysicianNet, For consumer free samples, Sample of the Future, RxCentric, MedManage Tracks, MedManage Leads Shift, and Peyrelevade.

6. Claim 52 is rejected under 35 U.S.C. § 103(a) as unpatentable over MedManage Leads Shift and Peyrelevade.

7. Claims 44 is rejected under 35 U.S.C. § 103(a) as unpatentable over RxCentric, Feeney, and Peyrelevade.

---

[1] The text of the rejection of claim 1set forth in the Examiners Answer describes this rejection as being made with only the two references that are cited here. The listing of claim 1 in the rejection under 35 U.S.C. § 103(a) as unpatentable over MedManage, RxCentric, Sample of the Future, and Peyrelevade is therefore considered a typographical error in the Answer (see Ans. 6-7).

THE ISSUES

At issue is whether the Appellants have shown that the Examiner erred in making the aforementioned rejections.

FINDINGS OF FACT

We find the following enumerated findings of fact (FF) are supported at least by a preponderance of the evidence.[2] Additional facts may appear in the Analysis section below.

FF1. *Medmanage Leads to Shift in Drug Sampling Practice Online Vouchers* discloses a system in which physicians are provided with online access to vouchers for free samples of specific medications. The physician hands the printed vouchers to the patient, and the patient can take the voucher to a pharmacy to receive the sample medication free of charge (ppgh. 2).

FF2. Peyrelevade has disclosed a system for constructing first and second websites that may incorporate common information while each incorporating information unique to each website (Abstract). One module may provide information for a first website, an alternative set of information for a second website, and a third set of information for both the first and second websites [0009].

FF3. Peyrelevade discloses that to identify the consumer that a cookie may be read on the processor associated with the consumer [0082].

---

[2] *See Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Patent Office).

FF4. Peyrelevade at [0083] discloses that using a profile for the request (that describes the consumer or consumer's purchasing history) the supplier website can customize the information provided to a reseller website or the consumer.

FF5. Peyrelevade at [0089] discloses that the computing platform may define rules to include a list of products offered by a retailer and enable display of only products offered by the retailer.

FF6. *Webster's New World Dictionary Third College Edition*, Simon and Shuster, 1998 provides a definition of "characteristic" as "1. A distinguishing trait, feature, or quality; peculiarity".

ANALYSIS

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner has rejected of claim 1 under 35 U.S.C. § 112, first paragraph, for failure to convey that the inventors, at the time the application was filed, had possession of the invention because the Specification fails to provide support for both claim limitation [1] and also for a recitation that the "same prescriber open[s] the drug sample web site and the same prescriber open[s] the drug sample Web site within another brand Web site" (Ans. 4-5).

In contrast, the Appellants argue that the cited rejection is in error and that support is given for claim limitation [1] in the Specification at 7:6-18 and 11:6-28 (Br. 6, 20-22).

We agree with the Appellants. The factual inquiry for determining whether a specification provides sufficient written description for the claimed invention is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant

was in possession of the invention as now claimed. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

Claim 1 includes the following text which includes claim limitation [1]:

> a computer-readable set of brand rules for guiding a distribution of drug samples of a drug to cause a [1] prescriber's drug sample availability and characteristics while a member of one brand Web site to be different from the same prescriber while a member of another brand Web site. (Claim 1).

Here, a review of the Specification at 7:6-18 shows that support is provided for claim limitation [1] by the Specification's disclosure for instance that "The set of brand rules 206 may cause one prescriber's drug sample availability and characteristics to be different than those of another prescriber" and the "personalization capabilities to tailor the distribution of drug samples" including "brand Web sites" (Spec. 7:6-18).

The Examiner has also found that the Specification does not provide support for the recitation that the "same prescriber open the drug sample web site and the same prescriber open the drug sample Web site within another brand Web site" (Ans. 4-5) but this exact quote is not found in claim 1 and the Examiner has failed to provide a prima facie case for the rejection in this regard. Regardless, claim 1 contains similar claim limitation [3] which the Examiner may have been referring to and which we will review. Claim limitation [3] requires "a prescriber identifier and a partner identifier

so as to open the computer-implementable drug sample fulfillment platform within the brand Web site or the brand Web site" and support for this claim limitation [3] is found in the Specification at 11:6-14. For these reasons the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, is not sustained. The Examiner has presented the same rationale for rejecting the other cited claims under this rejection and the rejection of these claims is not sustained for these same reasons.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner has determined that the rejection of claims 1, 6, 16, 21, and 31 is improper because the claim limitation [1] is indefinite. The Examiner also has determined that claim 6 recites "one or more third party sites depending on an exchanged transaction that includes a prescriber identifier so as to open the drug sample Web site within the third party site instead of another third party site" which is indefinite (Ans. 5).

In contrast, the Appellants have argued that this rejection is improper (Br. 23-27).

We agree with the Appellants. The test for definiteness under 35 U.S.C. § 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.,* 806 F.2d 1565, 1576 (Fed. Cir. 1986) (citations omitted). The claim limitation [1] that has been cited by the Examiner is supported in the Specification (see section above) and one of ordinary skill in the art would understand what is being claimed for the cited claim limitation [1]. For these reasons the rejection of the claims under 35 U.S.C. § 112, second paragraph is not

sustained. With specific regard to claim 6, those skilled in the art would understand what is being claimed when the cited claim limitation from claim 6 was read in light of the Specification since the term "third party site" would refer to a third party site in the transaction in some manner. For this reason the rejection of claim 6 under 35 U.S.C. § 112, second paragraph is not sustained as well.

Rejection under 35 U.S.C. § 103(a)

The Appellants argue that the rejection of claim 1 is improper because the Peyrelevade reference does not teach "a computer-readable set of brand rules….to cause a prescribers drug sample availability and characteristics while a member of one brand Web site to be different from the same prescriber which a member of another brand Web site" (Br. 29-33). The Appellants also argue that the references have been improperly combined (Br. 33-41).

In contrast, the Examiner has determined that Peyrelevade teaches or suggests this claim limitation at paragraphs 00009-0011, 0082-0083, and 0093 (Ans. 7, 23). The Examiner has also determined that the references are properly combined (Ans. 7).

We agree with the Examiner. We first construe the meaning of the words "availability and *characteristics*" (emphasis added) as used by the Appellants in the claims. We determine the scope of the claims in patent applications "not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction 'in light of the specification as it would be interpreted by one of ordinary skill in the art.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc) (*quoting In re Am.*

Acad. of Sci. Tech. Ctr., 367 F.3d 1359, 1364 (Fed. Cir. 2004)). We must be careful not to read a particular embodiment appearing in the written description into the claim if the claim language is broader than the embodiment. See *Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) ("Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.") The challenge is to interpret claims in view of the specification without unnecessarily importing limitations from the specification into the claims. See *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369 (Fed. Cir. 2003). Here, the Specification at page 7:6-18 states:

> After the brand manager 204 has selected a group of prescribers 210, the brand manager 204 produces a set of brand rules 206 which define the availability of drug samples to each of the prescribers 210. The set of brand rules 206 may cause one *prescriber's drug sample availability and characteristics* to be different from those of 10 another prescriber. Thus, for each prescriber there is a *virtual drug sample cabinet tailored specifically for that prescriber*. Preferably, the group of prescribers 210 is divided into segments. The brand rules provide personalization and customization for each segment. *Many other personalization capabilities to tailor the distribution of drug samples to prescribers 210 are possible, such as* various delivery methods; various drug 15 strengths; *trademark and local presentation of drug samples*; *customized drug disclaimers; specific product, package*, and brand Web sites; and facilitating the scheduling of prescriber interactions with sales representatives or medical science liaisons. (emphasis added).

Here, the Specification at 7:6-18 provides no express definition of what the term "*characteristic*" includes or excludes but the Specification's described *personalization capabilities* for the drug sample include not only drug strengths, but also *trademarks*, local *presentation*, customized *disclaimers*, and specific product *packages*. Thus, giving the term "characteristic" its broadest reasonable interpretation in light of the Specification does not exclude the term from including product presentation, packaging, or displayed information in some manner. A common dictionary definition of the word "characteristic" defines the term to include a "trait" (FF6) and the term "trait" of something could be broadly considered to include "information" provided with it as well.

Now turning to the references used in the rejection, *Medmanage Leads* has disclosed that physicians are provided with online access to vouchers for free samples of specific medications to be distributed to patients (FF1). Peyrelevade has also disclosed a system for constructing first and second websites that may incorporate common information while each incorporating *information unique to each website* (FF2) and identifying consumers with a cookie may be read on the consumer's processor (FF3). Peyrelevade also discloses that by using a profile for the request (that describes the consumer or consumer's purchasing history) the supplier website can *customize the information provided to a reseller website or the consumer* (FF4). Peyrelevade also discloses that the computing platform may define rules to include a list of products offered by a retailer and *enable display of only products offered by the retailer* (FF5). Thus, Peyrelevade has disclosed the customization of information related the reseller website or consumer.

The modification of the system of *Medmanage Leads* to include personalized information at respective websites for vendors or physicians is considered an obvious, predictable combination of known elements in order to provide information that is specific to each vendor and physician based on their stock of the drug sample and permissions to access certain drug samples in view of the teaching of customized information at a website taught by Peyrelevade. While Peyrelevade does not relate specifically to the distribution of drug samples, it does provide the teaching of customized information at a website that has been used in the rejection by the Examiner.

For these reasons the rejection of claim 1 and its dependent claims, which have not been separately argued, is sustained. Claim 6 contains a similar claim limitation and the rejection of this claim and its dependent claims under this rejection is sustained for these same reasons.

For independent claims 16, 21, and 31 the Appellants refer to the argued limitation in claim 1 discussed above, but such a claim limitation is not present in any of claims 16, 21, or 31.

With regard to claim 16, the Appellants specifically argue that the cited references fail to teach or suggest that "the drug sample fulfillment platform electronically notifies the prescriber when the prescriber has not ordered drug samples for a certain amount of time" (Br. 66-67). In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) the Court stated that when considering obviousness that "the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR* at 418. The modification of the prior art to include such a feature would have been readily inferred by

one of ordinary skill in the art since a variety of businesses track customers purchasing records and the elapsed time since an order was placed to increase business. For this reason the rejection of claim 16, and its dependent claims, which have not been separately argued is sustained.

With regard to claim 21, the Appellants specifically argue that the cited references fail to disclose "the time frame, dosages and quantity being different depending on whether the prescriber is a member of the one third party site or a member of another third party site" (Br. 49). The Examiner has determined that such a claim limitation would be obvious based on the inherency of drug expiration dates, *MedManage tracks troublesome pills*, and Peyrelevade (Ans. 42-43). We disagree with the Examiner. There is no articulated reasoning with rational underpinnings as to why the references would be modified in such a manner to have the "time frame, *dosages*, and quantity being different" depending on the prescriber's membership with the third party sites. For this reason, the rejection of claim 21 and its dependent claims is *not* sustained.

With regard to claim 31 the Appellants specifically argue that the prior art does not teach or suggest "discontinuing redemptions through a pharmacy network by the drug sample fulfillment program and disabling orders for drug samples in a sample that has expired" (Br. 61). In contrast, the Examiner has asserted that it is old and well known to disable online orders for unavailable items and that such a modification would have been obvious (Ans. 15). We agree with the Examiner. The modification of a drug fulfillment system to not ship drug samples that have expired is considered an obvious modification to only have drugs that have not expired

be shipped. For this reason the rejection of claim 31 and its dependent claims, which have not been separately argued, is sustained.

DECISION

The Examiner's rejection of claims 1-2, 4-10, 16-20, 31, 33-45, and 51-55 sustained.

The Examiner's rejection of claims 21-25 is reversed.

AFFIRMED-IN-PART

MP